K024343

USBiomaterials Corporation
13709 Progress Blvd., #23
Alachua, FL 32615
USA

JUL 11 2003

9.0 510(K) SUMMARY

9.1 Submitter's Name and Contact Information

Contact Person: David C. Greenspan, Ph.D., Vice President & Chief Technology Officer
Phone: 386.418.1551 Fax: 386.418.1465
Email: greenspan@usbiomat.com
Submitter Company: USBiomaterials Corporation
13709 Progress Blvd, #23
Alachua, FL 32615
Date Prepared December 23, 2002

9.2 Name of Device and Name/Address of Applicant

Butler GUM® Prophylaxis Paste with NovaMin®

USBiomaterials Corporation
13709 Progress Blvd., #23
Alachua, Florida 32615

9.3 Name and Address of Manufacturer

Germiphene Corporation
P.O. Box 1748
Brantford ON
Canada N3T 5V7
1379 Colborne St., E.
Brantford ON
Canada N3T 5M1

9.4 Common or Usual Name

Prophylaxis Paste

9.5 Classification Name

Oral cavity abrasive polishing agent 872.6030

9.6 Predicate Device

ProClude® K002989

9.7 Intended Use

Bulter GUM® Prophylaxsis Paste with NovaMin® is intended for use in a professionally administered cleaning and polishing procedure during the prophylaxis treatment. The NovaMin® in the paste reduces sensitivity by occluding dentinal tubules.

9.8 Technological Characteristics and Substantial Equivalence

All of the components found in Bulter GUM® Prophylaxis Paste with NovaMin® have been used in the predicate device, or have been found to be safe for dental use. NovaMin® is a sodium-calcium-phosphosilicate particulate that has been shown to

physically occlude dentinal tubules in the same manner as the calcium carbonate/arginine complex in the predicate device, ProClude® (K002989). Studies have concluded that NovaMin® is a non-irritant, and non-sensitizer, and is non-toxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2003

David C. Greenspan, Ph. D.
Vice President, Chief Technology Officer
US Biomaterials Corp
13709 Progress Boulevard, Suite 23
Alachua, Florida 32615

Re: K024343
Trade/Device Name: Butler Gum Prophylaxis Paste with NovaMin®
Regulation Number: 872, 6030
Regulation Name: Oral Cavity abrasive polishing agent
Regulatory Class: II
Product Code: EJR
Dated: April 9, 2003
Received: April 14, 2003

Dear Dr. Greenspan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

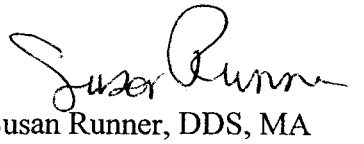
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594- 4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Deices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

USBIOMATERIALS CORPORATION
13709 PROGRESS BLVD., #23
ALACHUA, FL 32615
USA

1.0 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K024343

Applicant: USBiomaterials Corporation
13709 Progress Blvd., #23
Alachua, FL 32615
Phone: 386.418.1551
Fax: 386.418.1465

Device Name: Prophylaxis Paste with Bioactive Glass

Proprietary Name: Butler GUM® Prophylaxis Paste with NovaMin®

Indications For Use:

Butler GUM® Prophylaxis Paste with NovaMin® is intended for cleaning and polishing procedures as a part of a professionally administered dental prophylaxis treatment. Secondarily, Butler GUM® Prophylaxis Paste with NovaMin® can be used for the immediate relief of tooth sensitivity, post-scaling and root planing.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K024343

Prescription Use ✓ OR Over-The-Counter Use _____
(Optional Format 1-2-96)